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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/797,035	03/11/2004	Satoshi Kitamura	1975.1004	4549
21171 7590 02/04/2009 STAAS & HALSEY LLP SUITE 700 1201 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005				
EXAMINER				
KALLIS, RUSSELL				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/797,035

Applicant(s)

KITAMURA ET AL.

Examiner

RUSSELL KALLIS

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Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 October 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-7 and 10-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5-7 and 10-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 October 2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claims 5-7 and 10-14 are pending and examined.

Drawings

The drawings in combination with the color photographs should suffice for publication.

Examiner comment

The rejection formulated 5/30/2008 did not include within the rejection the language of sections (ii) and (iii) of Claims 5 and 6 and section (b) of claim 10 and 11. However, those limitations are believed to be substantially co-extensive in scope with the previously rejected 60% nucleotide identity language. Therefore, a second non-final is presented below that addresses those aspects of Applicants' claims. The Examiner apologizes for this short coming and any delay.

Claim Rejections - 35 USC § 112

Claims 5-7 and 10-14 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to plants and plant cells transformed with a nucleotide sequence of SEQ ID NO: 1 having deletions, substitutions or additions of one or more bases to SEQ ID NO: 1; and a nucleotide sequence that hybridizes under stringent conditions defined in paragraph 0050 of the specification as 6XSSC and 5X Denharts hybridizing at a temperature as low as 25 C°; and that compartmentalize

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proanthocyanidins into plant vacuoles; and methods of producing proanthocyanidins therewith.

Applicant describes SEQ ID NO: 1 encoding SEQ ID NO: 2 having the activity of compartmentalizing proanthocyanidins into the vacuoles of plant cells.

Applicant does not describe polynucleotide sequences of SEQ ID NO: 1 having deletions, substitutions or additions of one or more bases to SEQ ID NO: 1; and nucleotide sequences that hybridizes under stringent conditions defined in paragraph 0050 of the specification as 6XSSC and 5X Denharts hybridizing at a temperature as low as 25 C° and that have the activity of compartmentalizing proanthocyanidins into the vacuoles of plant cells.

The Federal Circuit has recently clarified the application of the written description requirement to inventions in the field of biotechnology. The court stated that, “A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus.” *See University of California v. Eli Lilly and Co.*, 119 F.3d 1559; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Applicants fail to describe a representative number of polynucleotide sequences of SEQ ID NO: 1 having deletions, substitutions or additions of one or more bases to SEQ ID NO: 1; and nucleotide sequences that hybridizes under stringent conditions defined in paragraph 0050 of the specification as 6XSSC and 5X Denharts hybridizing at a temperature as low as 25 C° that compartmentalize proanthocyanidins in the vacuoles of plant cells. Applicants only describe SEQ ID NO: 1 from *Arabidopsis* encoding SEQ

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ID NO: 2 that compartmentalizes proanthocyanidin in the vacuoles of plant cells.

Furthermore, Applicants fail to describe structural features common to members of the claimed genus of polynucleotide or amino acid sequences that compartmentalize proanthocyanidins in plant cells. Hence, Applicants fail to meet either prong of the two-prong test set forth by *Eli Lilly*. Furthermore, given the lack of description of the necessary elements essential for polynucleotide or amino acid sequences that compartmentalize proanthocyanidins in plant cells, it remains unclear what features identify the broadly claimed genus. Since the genus of proanthocyanidin compartmentalizing polynucleotides or amino acid sequences has not been described by specific structural features, the specification fails to provide an adequate written description to support the breadth of the claims.

Polynucleotide sequences of SEQ ID NO: 1 having deletions, substitutions or additions of one or more bases to SEQ ID NO: 1; and nucleotide sequences that hybridizes under stringent conditions defined in paragraph 0050 of the specification as 6XSSC and 5X Denharts hybridizing at a temperature as low as 25 C° encompass naturally occurring allelic variants, as well as sequences encoding proteins having no known proanthocyanidin compartmentalizing activity, of which Applicant is not in possession. Accordingly, the specification fails to provide an adequate written description to support the genus of proanthocyanidin compartmentalizing polynucleotide coding sequences or amino acid sequences encompassed by the percent identity language as set forth in the claims.

For example, Alfenito, teaches transformation of with *Arabidopsis* clone H36860 that encodes a type I GST protein having deletions, substitutions or additions of one or

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more bases to SEQ ID NO: 1; or transformation with nucleotide sequences that hybridize under stringent conditions defined in paragraph 0050 of the specification as 6XSSC and 5X Denharts hybridizing at a temperature as low as 25 C° and that have the activity of compartmentalizing proanthocyanidins into the vacuoles of plant cells

SEQ ID NO: 1 (see previously submitted attached sequence report #2 that teaches at least 75% sequence identity to SEQ ID NO: 1; see p. 1138 section C the H36860 sequence is the ATU 70672 sequence of attachment #2; and last paragraph of introduction on page 1137 in column 2). However, the presence of a wild type copy of H36860 in the *tt19* mutant of *Arabidopsis* did not result in the production of proanthocyanidins in the seed coat of *Arabidopsis* seeds. This indicates that not all sequences falling within the broadly claimed genus will compartmentalize proanthocyanidins in plants. Amending the language of claims 5 and 6 and claims 10 and 11 in the next to last line to include “wherein the nucleotide sequence encodes a protein having 90% sequence identity to SEQ ID NO: 2 and” would obviate this rejection.

Claims 5-7 and 10-14 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for plant cells and plants transformed with SEQ ID NO: 1 encoding SEQ ID NO: 2 and methods of producing proanthocyanidins in plants therewith, does not reasonably provide enablement for plant cells or plants transformed with polynucleotide sequences of SEQ ID NO: 1 having deletions, substitutions or additions of one or more bases to SEQ ID NO: 1; and nucleotide sequences that hybridizes under stringent conditions defined in paragraph 0050 of the specification as 6XSSC and 5X Denharts hybridizing at a temperature as low as 25 C° that compartmentalize proanthocyanidins in the vacuoles of plant cells. The

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specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands*, 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

The claims are broadly drawn to plants and plant cells transformed with a nucleotide sequence of SEQ ID NO: 1 having deletions, substitutions or additions of one or more bases to SEQ ID NO: 1; and a nucleotide sequence that hybridizes under stringent conditions defined in paragraph 0050 of the specification as 6XSSC and 5X Denharts hybridizing at a temperature as low as 25 C°; and that compartmentalize proanthocyanidins into plant vacuoles; and methods of producing proanthocyanidins therewith.

Applicants teach SEQ ID NO: 1 encoding SEQ ID NO: 2 that compartmentalize proanthocyanidins into vacuoles of transformed plant cells and plants; and methods of producing proanthocyanidins therewith.

Applicants do not teach plants and plant cells transformed with polynucleotide sequences of SEQ ID NO: 1 having deletions, substitutions or additions of one or more

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bases to SEQ ID NO: 1; or transformed with nucleotide sequences that hybridizes under stringent conditions defined in paragraph 0050 of the specification as 6XSSC and 5X Denharts hybridizing at a temperature as low as 25 C° and that have the activity of compartmentalizing proanthocyanidins into the vacuoles of plant cells.

The state-of-the-art is such that one of skill in the art cannot predict the activity of GST like type I proteins (i.e. polynucleotide sequences of SEQ ID NO: 1 having deletions, substitutions or additions of one or more bases to SEQ ID NO: 1; and nucleotide sequences that hybridizes under stringent conditions defined in paragraph 0050 of the specification as 6XSSC and 5X Denharts hybridizing at a temperature as low as 25 C° and that have the activity of compartmentalizing proanthocyanidins into the vacuoles of plant cells) absent undue trial and error experimentation.

For example, Alfenito, teaches transformation of with *Arabidopsis* clone H36860 that encodes a type I GST protein having a nucleotide sequence of SEQ ID NO: 1 having deletions, substitutions or additions of one or more bases to SEQ ID NO: 1; or a nucleotide sequences that hybridizes under stringent conditions defined in paragraph 0050 of the specification as 6XSSC and 5X Denharts hybridizing at a temperature as low as 25 C° and that have the activity of compartmentalizing proanthocyanidins into the vacuoles of plant cells (see previously submitted attached sequence report #2 that teaches at least 75% sequence identity to SEQ ID NO: 1; see p. 1138 section C the H36860 sequence is the ATU 70672 sequence of attachment #2; and last paragraph of introduction on page 1137 in column 2). However, the presence of a wild type copy of H36860 in the *tt19* mutant of *Arabidopsis* did not result in the production of proanthocyanidins in the seed coat of *Arabidopsis* seeds. This indicates that not all

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sequences falling within the broadly claimed genus will compartmentalize proanthocyanidins in plants.

Given the lack of guidance in the instant specification, undue trial and error experimentation would be required for one of ordinary skill in the art to isolate a myriad of polynucleotide sequences and test in a multitude of transformed plants for vacuolar compartmentalization of proanthocyanidins.

Therefore, given the breadth of the claims; the lack of guidance and working examples; the unpredictability in the art; and the state-of-the-art as discussed above, undue experimentation would be required to practice the claimed invention, and therefore the invention is not enabled throughout the broad scope of the claims. Amending the language of claims 5 and 6 and claims 10 and 11 in the next to last line to include “wherein the nucleotide sequence encodes a protein having 90% sequence identity to SEQ ID NO: 2 and” would obviate this rejection.

No claim is allowed.

The claims are deemed free of the prior art given the failure of the prior art to teach or reasonably suggest plant cells or plants transformed with SEQ ID NO: 1 that compartmentalize proanthocyanidin in vacuoles.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (571) 272-0798. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Russell Kallis/
Primary Examiner, Art Unit 1638
February 2, 2009

Application Number**Application/Control No.**

10/797,035

**Applicant(s)/Patent under
Reexamination**

KITAMURA ET AL.

Examiner

RUSSELL KALLIS

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